REMARKS

Status of the Claims

Claims 54-56, 59, 62 and 117-128 are currently pending. Claims 1-53, 57-58, 60-61, and 63-118 have been cancelled. Applicants thank the Examiner for the courtesies extended during the telephone interview of May 1, 2007 to discuss the pending claims, the prior art cited in the last Office Action and the proposed content for the Declarations under 37 C.F.R. § 1.132 filed herewith.

The pending claims were rejected in the Final Office Action dated December 1, 2006 as allegedly unpatentable under 35 U.S.C. § 103(a) as follows:

A. Claims 54-56 and 59 over Applicants' admission of the prior art in view of Saini et al.

B. Claim 62 over Applicants' admission of the prior art in view of Saini et al. as applied to Claim 54 and further in view of MARK V Injection System Brochure.

C. Claim 117 over Applicants' admission of the prior art in view of Saini et al. as applied to Claim 54 and further in view of Boyd.

D. Claims 118-119, 121-125, 127, and 128 over Applicants' admission of the prior art in view of Saini et al. and MARK V Injection System Brochure.

E. Claim 120 over Applicants' admission of the prior art in view of Saini et al. and MARK V Injection System Brochure as applied to Claim 118 and further in view of Boyd.

F. Claim 126 over Applicants' admission of the prior art in view of Saini et al. and MARK V Injection System Brochure as applied to Claim 124 and further in view of Blakeley et al.

Based on the following remarks, Applicants respectfully request reconsideration and allowance of the present claims.

I. Discussion of the Merits of the Examiner's December 1, 2006 Rejection and Declarations Filed Under 37 C.F.R. Section 1.132 Rebutting Such Rejection

Applicants respectfully request that the rejections of the pending claims be withdrawn, as the claims are patentable over the prior art cited by the Examiner. In support of the patentability of the claims, Applicants are submitting with this Response four Declarations pursuant to 37 C.F.R. Section 1.132. The Declaration of Dr. Bruce Rosen, M.D., Ph.D. responds to the analysis set forth in the Examiner's December 1, 2006 Final Rejection ("Examiner's rejection"), and also provides objective evidence of the commercial success of the MR injectors sold by Medrad, Inc. that embody the claimed invention, the difficulties Medrad faced in developing the claimed invention, and copying of the invention by a competitor of Medrad. The Declarations of William Snyder, Salvatore Dedola, and John Dick, Jr., also provide evidence of commercial success and other relevant objective evidence of the non-obviousness of the invention claimed in the above-captioned Patent Application.

Applicants respectfully submit that the Examiner's rejection should be withdrawn for the following principal reasons:

A) First, the references cited by the Examiner do not disclose each and every element of the claimed invention, either on their own or in combination. This point is addressed in detail herein and in the Declaration of Dr. Rosen.

B) Second, at the time of the invention, a person of ordinary skill in the art would not have known or been motivated to combine the references cited by the Examiner. The references in fact teach away from the Examiner's proposed combinations of references, and also teach away from the claimed invention itself. Moreover, the lack of available prior art devices that could effectively operate in the MRI environment demonstrates that the claimed invention would not have occurred in the ordinary course.

These points are fully documented in the enclosed Declaration of Dr. Rosen, a practitioner in the field of contrast-enhanced MR imaging at the time of the invention and a person of ordinary skill in the relevant art. Dr. Rosen's Declaration analyzes the relevant prior art references and identifies the errors in the Examiner's rejection in this regard.

C) Third, an analysis of the objective evidence of non-obviousness in the Declarations submitted herewith plainly shows that the invention claimed in the Patent Application is not obvious. Objective evidence of non-obviousness may rebut a *prima facie* case of obviousness based on prior art references. *See WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999); *see also* Chisum, Section 5.05[2][c][ii] FN 25, p. 5-667. The Supreme Court, in *KSR Int'l Co. v. Teleflex, Inc.*, recently confirmed the importance of reviewing secondary considerations. No. 04-1350 (U.S. Apr. 30, 2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). The Declarations submitted here provide powerful evidence of the overwhelming commercial success of the claimed invention, the difficulty of developing the

invention, and copying of the invention by a competitor, all of which demonstrate the patentability and non-obviousness of the claimed invention.

D) Fourth, Applicants respectfully submit that Examiner improperly considered the Applicants' prior work as prior art to the present invention. The Examiner asserted that certain text appearing in the specification of Applicants' U.S. Patent No. RE 36,602 (Col. 1, line 30 – Col. 2, line 22) amounted to an "admission of the prior art" by Applicants, but the Declaration of Dr. Rosen explains that this text was not a reference to any prior art, but was instead a description of Applicants' own experimental use of prototype devices that were part of the development leading to the present invention. As such, this material should not be considered to be prior art to the claimed invention.

In light of the points raised by Applicants and the Declaration evidence submitted herewith, it is respectfully submitted that the claimed invention is patentably distinguishable over the prior art, and it is requested that all of the pending claims be formally allowed. Upon careful review of the references it is believed the Examiner will agree with this proposition.

II. Discussion of the Merits of the Examiner's Rejection

As discussed above, Applicants respectfully submit that the Examiner's rejection was improper for four main reasons. These reasons are discussed in turn below.

A. The References Cited By the Examiner Fail to Disclose Each and Every Element of the Claimed Invention

Pursuant to MPEP § 2143, to establish a *prima facie* case of obviousness, the prior art references must teach or suggest all the claim limitations. *See also In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988); *Litton Industrial Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158 (Fed.

Cir. 1985) (internal quotation and citations omitted); *In re Ostahowski*, 2006 WL 2822255, *2 (Bd. Pat. App. & Interf. September 29, 2006 (holding that the Examiner failed to establish obviousness because the combination of references failed to teach every claimed element); *In re Mou*, 1997 WL 33122281 (Bd. Pat. App. & Interf. 1997); *In re Kondo*, 1996 WL 1748654 (Bd. Pat. App. & Interf. 1996); *In re Corry*, 1996 WL 1805909 (Bd. Pat. App. & Interf. 1996); *In re Toshiharu*, 1996 WL 1748654 (Bd. Pat. App. & Interf. 1996) ("Lastly, the examiner further has failed to establish ... obviousness, since the examiner has not accounted for every limitation in the claim.").

Here, the references cited in the Examiner's rejection, even when combined, do not disclose each and every element of the invention claimed in the Patent Application. A discussion of the current rejections and the references cited by the Examiner is presented below. It should also be noted that the Declaration of Dr. Rosen also provides a detailed discussion of the Examiner's rejection and the references cited by the Examiner.

1. The Claimed Feature of Two Drive Mechanisms

The Examiner rejected claims 62 and 118-128, which require two syringes and two drive mechanisms, in view of a combination of references including the *Saini et al.* article and the MARK V Injection System Brochure. Notably, it was acknowledged by the Examiner in the Office Action of December 1, 2006 that these references do not disclose the use of two syringes and two drive mechanisms, and Applicants submit that there is no evidence before the Examiner that indicates that a person having ordinary skill would have known to further modify the prior art to include two drive mechanisms.

In fact, the Declaration of Dr. Rosen, a co-author of the *Saini et al.* article, states that he and his fellow co-authors did not know to modify an injector to include two drive mechanisms, and that they considered a fundamentally different approach from the claimed invention. *See* Rosen Dec., ¶ 22-25. The *Saini et al.* article describes an injector with a single syringe. On page 751 (MD123699) of the article, the authors, including Dr. Rosen, state:

> the major impediment for routine clinical use is the absence of a set-up that will allow the contrast agent to be flushed out of the connecting tubing. Such a system is needed to reduce waste of the contrast medium and to prevent its stasis in the arm. A potential solution may be gently to aspirate gadopentetate dimeglumine after saline has been preloaded into the syringe. ... Alternatively, specially designed compartments ... can be devised that can be placed between the syringe and the connecting tubing.

Thus, instead of suggesting the use of two syringes and two drive mechanism to allow the injection of contrast solution and saline solution, the *Saini et al.* article proposes an entirely different solution of loading ("aspirating") a single syringe with separate layers of contrast and saline, or alternatively adding a special compartment. (*Saini et al.*, page 751 (MD123699)). The claimed invention's feature of two syringes and two drive mechanisms in an MR injector is nowhere taught or suggested in the *Saini et al.* article.

2. The Claimed Feature of a Substantially Non-Reactive Communication Control Link

The Examiner rejected Claims 54-56, 59, 62, 117-128, which require a substantially non-reactive communication control link, under Section 103 in view of the *Patient Anesthesia & Monitoring* article, in combination with other references. The Examiner stated that this reference's use of fiber optic communication links in the MR environment to prevent EM interference discloses a substantially non-reactive communication control link. *See, e.g.,*

Examiner's Dec. 1, 2006 Rejection at pp. 2-3. Applicants respectfully submit that the Examiner's citation to the *Patient Anesthesia and Monitoring* article was improper for two reasons. (Rosen Dec., ¶¶ 26-29).

First, the claimed invention requires a *communication control link*, but the *Patient Anesthesia and Monitoring* article only discloses a "communications link." This issue is addressed in more detail in the Declaration of Dr. Rosen. (Rosen Dec. at ¶ 27). Second, the article describes systems where some RF interference is observed, and Applicants submit that this article does not teach the arrangement of the claimed invention, in which a substantially non-reactive communication control link connects a system controller outside the shielded room and an injector control unit inside the shielded room. (Rosen Dec. at ¶ 28).

The *Patient Anesthesia & Monitoring* article does not disclose a substantially non-reactive communication control link and, as a result, this claim limitation is not disclosed in the prior art. All of the pending claims are allowable and the rejection of the pending claims on this basis should be withdrawn by the Examiner.

3. The Claimed Feature of a System Controller Outside and an Injector Control Unit Inside the Shielded Room

All of the pending claims require a system controller outside the shielded room and an injector control unit inside the shielded room – a claimed feature that is not found in the prior art. Applicants respectfully submit that the rejection was improper for this reason as well.

As described in more detail in the Declaration of Dr. Rosen (¶ 35), the prior art references applied by the Examiner do not disclose a distribution of control between a system controller outside the shielded room and an injector control unit inside the shielded room. The *Saini et al.*

article identifies all the control in a component within the shielded room while the Mark V materials show all the control outside the shielded room. Meanwhile, the *Patient Anesthesia & Monitoring* article shows having all of the control either entirely inside or entirely outside, but not distributed between two components. (Rosen at ¶ 35).

Therefore, the Examiner's rejection is improper for this reason as well and Claims 54-56, 59, 62 and 117-128 are allowable over the prior art.

B. A Person Having Ordinary Skill in the Art Would Not Have Known to or Been Motivated to Combine the References Cited by the Examiner

The Supreme Court recently made it clear that the teaching, suggestion and motivation test, while not to be rigidly applied, is still informative for determining obviousness. *KSR Int'l Co.*, No. 04-1350 (U.S. Apr. 30, 2007). Moreover, the Supreme Court emphasized that a rejection under § 103(a) must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the manner claimed. *KSR*, slip op. at 14; *see also* MPEP § 2143 (citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). This approach still requires "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999) (citing *Fine*, 837 F.2d at 1074) ("And teachings of references can be combined *only* if there is some suggestion or incentive to do so.") (internal quotation marks and citation omitted)); *In re Theurer*, 2006 WL 1665553 (Bd. Pat. App. & Interf. 2006) (It is well settled that in order to establish a prima facie case of **obviousness** under § 103(a), the examiner must show that some objective teaching, suggestion or motivation in the applied prior art taken as a whole

and/or knowledge generally available to one of ordinary skill in this art would have led that person to the claimed invention as a whole...") (internal citations omitted).

Here, a person of ordinary skill in the art would not have been motivated to combine the references cited in the Examiner's rejection. The Declaration of Dr. Rosen, a skilled artisan, confirms this in much greater detail. (Rosen Dec. at ¶¶ 30-34).

Moreover, the references cited in the Examiner's rejection teach away from their combination. *See Fine*, 837 F.2d at 1075. For example, the *Saini et al.* reference discloses an injector with the system controller inside the shielded room. (Rosen Dec. at ¶ 32).

Moreover, the *Saini et al.* article, which described a Mark V injector, discloses an injector that used only a single drive mechanism to drive a syringe. The authors of the article, which included Dr. Rosen, suggest two solutions to the single syringe problem discussed above, neither of which related at all to the claimed invention here. (Rosen Dec. at ¶¶ 22-25). Likewise, there are other examples in the references cited in the Examiner's rejection of teaching away from the invention of the Patent Application. These examples are spelled out in greater detail in Dr. Rosen's Declaration. (Rosen Dec., ¶¶ 32-33).

C. Secondary Considerations Plainly Show that the Invention of the Patent Application is Patentable and Non-Obvious

Applicants respectfully submit that the Examiner failed to consider secondary considerations of non-obviousness. The Supreme Court however recently stated that secondary considerations of non-obviousness are important and must be considered in any obviousness determination. *See KSR Int'l Co.*, No. 04-1350 (U.S. Apr. 30, 2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

The attached declarations discuss in detail various secondary considerations:

Dr. Bruce Rosen:

Dr. Rosen, a co-author of the *Saini et al.* article, is a person of ordinary skill in the art. (Rosen Dec. at ¶¶ 1-5). Dr. Rosen confirms the commercial success of Medrad's products and establishes the nexus between the commercial success and the aspects claimed in the Patent Application. (Rosen Dec. at ¶¶ 8-13). Dr. Rosen also identifies copying of the claimed invention by a competing company. (Rosen Dec. at ¶¶ 14-18). Dr. Rosen further states that a non-reactive injector system that incorporates two syringes was unknown in the art prior to the invention, and the characteristics of such a system make it commercially desirable. (Rosen Dec. at ¶¶ 22-25). Dr. Rosen also comments on the difficulties of developing an injector that effectively operates in the harsh MR environment. (Rosen Dec. at ¶ 6-7).

Finally, Dr. Rosen analyzes the references cited in the Examiner's rejection. In particular, Dr. Rosen identifies the elements missing from those references and states that there was no knowledge in the art nor a motivation to combine the references in the manner described in the Examiner's rejection. (Rosen Dec. at ¶¶ 26-35). Dr. Rosen concludes that the invention claimed in the Patent Application is not obvious in view of the references cited by the Examiner.

William Snyder:

William Snyder, Medrad's Executive Director of Finance, identifies the overwhelming commercial success of the Applicant's products embodying the invention of the Patent Application. (Snyder Dec. at ¶¶ 3-7). In particular, Mr. Snyder states that Medrad has experienced over $250 million in sales of the commercial products embodying the claimed

invention. (Snyder Dec. at ¶¶ 3-4). Mr. Snyder also confirms that, in the United States, the Applicant enjoys a market share of approximately 85%. (Snyder Dec. at ¶ 7).

John Dick Jr.:

John Dick Jr., an employee of a customer of Medrad that purchased and uses the commercial embodiment of the claimed invention, identifies in his declaration the benefits of the commercial products. (Dick, Jr. Dec. at ¶ 7-10). Mr. Dick confirms that aspects of the invention that are claimed in the Patent Application make the products commercially desirable. (Dick, Jr. Dec. at ¶ 6-10). Mr. Dick provides a nexus therefore between commercial success and the claimed invention.

Salvatore Dedola:

Salvatore Dedola, one of the named inventors of the claimed invention and a person having ordinary skill in the art, identifies in his Declaration the difficulties experienced by the Applicant in developing the invention and the skilled attempts to achieve the invention made by the Applicant. (Dedola Dec. at ¶ 5-10). Mr. Dedola also reiterates the commercial success of the products and establishes that any success is a result of the claimed invention. (Dedola Dec. at ¶ 11-13).

D. Applicants Respectfully Submit that the Examiner Improperly Used Medrad's Discussion of Its Own Work as an "Admission of Prior Art" for Section 103 Obviousness Rejection

The Examiner cited "Applicant's admission of prior art" as disclosing a patient infusion system for use with an MRI system having an infusion apparatus positioned within a shielded room and the system controller located external to the room, wherein the infusion apparatus

includes an injector and a motor to operate the injector. The Examiner used this "reference" to reject claims 54-56, 59, 62, 117-128.

Applicants respectfully submit that the Examiner's rejection inappropriately uses the Applicants' own work as prior art. In particular, the Examiner stated with respect to every application claim rejected: "rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission of the prior art …." The "Applicant's admission of the prior art," however, is not a discussion of prior art at all and is instead a discussion taken from the specification of U.S. Patent No. RE36,602 (Col. 1, line 30 – Col. 2, line 22) and this Application describing Applicants' experimental use of prototype devices that were part of the development leading to the present invention.

As a general principle, an inventor's own prior original work cannot be cited as part of the prior art to show that his later invention is obvious under Section 103. *See Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003); *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003) ("One's own work may not be considered prior art in the absence of a statutory basis … ."); *see also* Note 251, Chisum, § 5.03[3][f].

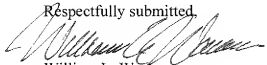
In this case, the Examiner cited the Applicants' earlier attempts to solve the problems associated with using a patient infusion system in MRI. Specifically, the Applicants' discussion of the earlier devices refers to the experimental testing of Applicants' own prototype injectors, which was performed under the close supervision of the Applicants and was not the work of anyone else. Dr. Rosen used one of the experimental prototype devices in his work at MGH as part of Applicants' development of the claimed invention. The Declaration of Dr. Rosen confirms that this testing took place. (Rosen Dec. at ¶ 7 and 21). Applicants submit that the

prototype device used by Dr. Rosen, and others, was the system described by Applicants in this Application and U.S. Patent No. RE36,602 (col. 1, line 30 – col. 2, line 22). Thus, the referenced discussion should not be used as cited to reject claims 54-56, 59, 62, 117-128.

In view of the foregoing remarks, the claims are believed to be in condition for allowance and a Notice to that effect is respectfully requested.

The Examiner is encouraged to call the undersigned attorney at 404-853-8081 if doing so will facilitate prosecution of the application. No fees are believed to be due at this time. However, the Commissioner is hereby authorized to charge any additional fees due or credit any overpayment to Deposit Account 19-5029 (Ref.: 23578-0010).

Respectfully submitted,



William L. Warren
Reg. No. 36,714

SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street, NE
Atlanta, Georgia 30309-3996
Phone: 404.853.8000
Fax: 404.853.8806
Attorney Docket No.: 23578-0010